The Contaminant Candidate List: Determining the Need for Future Drinking Water Standards

Briefing for

The Science Advisory Board

June 11, 2002

What is the purpose of today's meeting?

- Discuss development of the Contaminant Candidate List and process for making regulatory determinations
- Describe Federal Register Notice requesting comment on preliminary regulatory determinations
- Outline next steps

What does the SDWA require?

- Develop list of new contaminants to consider for regulation: Done in March 1998
- Determine whether to regulate at least 5 new contaminants from the List: Statutory Deadline was August 2001
- Develop regulations: Future (proposal 24 months following decision to regulate, promulgate 18 months thereafter)
- Cyclical process, every 5 years

What is the standard setting agenda required by the SDWA?

(SDWA Section 1412)

1996 Priority Standards

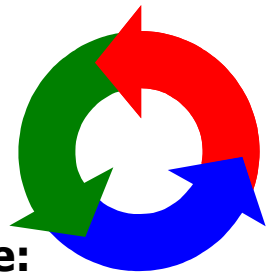
(1) Mandated by Congress:

- 1996 SDWA requires standards for specific contaminants (e.g. radon, arsenic, M/DBP Cluster, radionuclides).

Future Contaminants

(2) EPA determines what to regulate:

- 1996 SDWA requires identification of potential high-risk contaminants via Contaminant Candidate List (CCL) by February 1998.
- EPA required to determine whether at least 5 contaminants on list should be regulated by August 2001
- Contaminant selection and regulatory determination process repeated on a 5 year cycle.



Review Existing NPDWRs

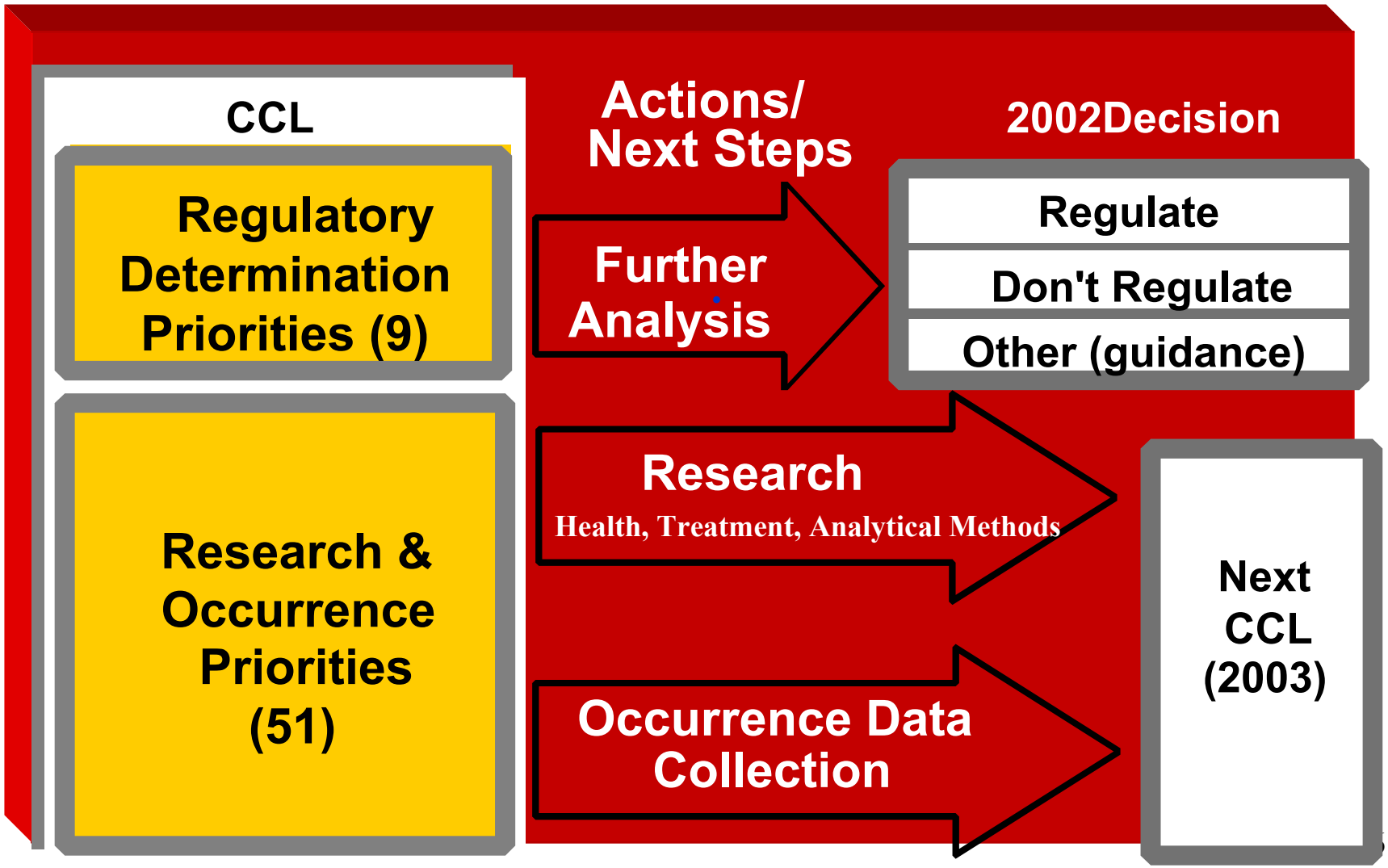
(3) <u>Re-evaluate</u> existing NPDWRs (1996 SDWA):

- Section 1412(b)(9): "*the Administrator shall, not less often than every 6 years, review and revise, as appropriate, each primary drinking water regulation … any revision shall maintain, or provide for greater, protection of the health of persons.*"
- Review of pre-1996 NPDWRs needs to be completed in 2002.
- Review of post-1996 NPDWRs will be included in future review rounds.

How do contaminants get on the List?

1. **Risk-based decision process**
   - Consider best available peer-reviewed science and information on health effects and occurrence
2. **Process**
   - EPA analysis
   - Peer review: Used recommendations of NDWAC
   - Consulted with the SAB
   - Public review: Sought public comment on draft CCL and held several stakeholder meetings
3. **Result**
   - March 1998 Final CCL list of 60 contaminants (10 microbial; 50 chemical)
   - 9 with sufficient information for regulation determination process
   - 51 require additional research/info on health effects, occurrence, treatment, or methodologies

What is the status of the various contaminants on the CCL?



Federal Register Notice

- Recommend Preliminary Regulatory Determinations for 9 contaminants:

Acanthamoeba	metribuzin
aldrin	naphthalene
dieldrin	sodium
hexachlorobutadiene	sulfate
manganese	

- Two remaining high-priority contaminants may be candidates for future "off-cycle" regulatory determination:

  perchlorate

  metolachlor

What analysis did we undertake to determine whether to regulate?

- SDWA requires consideration of 3 issues:
  - **Health Effects:** Establish an "estimated health reference level" concerning health effects;
  - **Occurrence:** Determine if contaminant occurs in public water systems with a frequency and at levels of public health concern; and
  - **Opportunity for risk reduction:** Determine if regulation would present a meaningful opportunity for health risk reduction.

-- Summary --
Recommended preliminary determinations: No regulatory action appropriate on any

Contaminant	**Rationale**
Manganese (see p. 25)	Low adverse health effects
Sulfate (new health advisory; see p. 29)	Low adverse health effects
Aldrin and dieldrin (see p. 23)	Low occurrence at levels of concern
Hexachlorobutadiene (see p. 24)	Low occurrence at levels of concern
Metribuzin (see p. 26)	Low occurrence at levels of concern
Naphthalene (see p. 27)	Low occurrence at levels of concern
Acanthamoeba (guidance; see p. 22)	Lacks meaningful opportunity for risk reduction
Sodium (new health advisory; see p. 28)	Lacks meaningful opportunity for risk reduction

How did we address adverse health effects?

- **EPA analysis:**
  - Evaluate best available peer-reviewed studies and assessments
  - Describe adverse health effects and derive an "estimated health reference or benchmark level" for each contaminant
- **Review Process:**
  - Process recommended by NAS and NDWAC
  - Consulting with SAB on recommended process and "estimated health reference levels" during public comment period
  - Used only best available peer-reviewed data and analyses for regulatory determinations
- **Result:** Manganese and sulfate found to have low adverse health effects. Recommend health advisory for sulfate.

Recommended preliminary determinations based on health effects

Contaminant	Health Effect
Manganese	Toxicity very low when ingested
Sulfate (new health advisory)	Risk of adverse health effect is limited and acute and occurs at high concentrations. People either develop tolerance for high levels or limit consumption.

How did we address occurrence?

- **EPA analysis:**
  - Collected, screened, aggregated, and analyzed over 7 million analytical records
  - Developed national occurrence and exposure estimates - e.g., how many systems/people are at, or near, the "estimated health reference level"?
- **Review Process:**
  - Process recommended by NAS and NDWAC
  - Consulting with SAB on recommended process and estimated occurrence during public comment period
- **Result:**
  - Aldrin/dieldrin; hexachlorobutadiene; metribuzin; naphthalene were found to have low occurrence at levels of concern

Recommended preliminary determinations based on cross-section occurrence

Contaminant	**"Health Reference Level"** (median occurrence concentration)	**Number Systems > "Health Reference Level"**	**Pop. Exposed > "Health Reference Level"**
Aldrin and Dieldrin	**0.002** (Aldrin = 0.58) (Dieldrin = 0.16)	Aldrin = 2 Dieldrin = 11	Aldrin = 8,600 Dieldrin = 32,200
Hexachlorobutadiene	**1.0** (0.25 – 0.30)	Round 1 – 14 Round 2 - 4	Round 1– 263,000 Round 2 – 3,300
Metribuzin	**70** (0.10)	0	0
Naphthalene	**140** (0.74 – 1.0)	Round 1 – 1 Round 2 - 0	Round 1 –5,400 Round 2 - 0

How did we address a meaningful opportunity for health risk reduction?

- **EPA analysis:**
  - Alternative means to address risk reduction: e.g., guidance
  - Geographic distribution: e.g., local or national?
  - Use and release information: e.g., is it banned or has it been replaced? Are use trends increasing or decreasing?
  - Other routes of exposure: e.g., inhalation
  - Contribution from other sources: e.g., air or food
- **Review Process:**
  - Process recommended by NAS and NDWAC
  - Consulting with SAB on recommended process and opportunity for risk reduction
- **Result:** *Acanthamoeba* and sodium are best addressed through guidance and health advisory (respectively)

Ongoing Work

- We are focusing, in particular, on filling data gaps for 2 additional CCL contaminants: metolachlor and perchlorate

- Preliminary information available:

Metolachlor:

- Herbicide, primarily used on corn crops. Second most widely used pesticide in US.

Perchlorate:

- Primarily associated with the manufacturing or testing of solid rocket fuels. Also found in the manufacturing and detonation of fireworks and produced in large scale as a component of automobile air bags.

What are the next steps?

- Publish Federal Register Notice requesting comment on preliminary determinations
- 60-day comment period
- Hold stakeholder meeting to discuss preliminary determinations
- SAB review of process and preliminary determinations
- Finalize notice late 2002

Appendix - Contaminant Profiles
Acanthamoeba

Background: Single celled microbes found in water habitats, soil, and dust. The organism can cause serious infection of the eye (keratitis) and the brain (GAE).

Health effects:

- Disease conditions
  - Acanthamoeba keratitis: Caused by direct exposure to contaminated water and either minor corneal trauma or wearing of contact lenses.
  - Granulomatous Amoebic Encephalitis (GAE): Occurs mostly in chronically ill individuals with compromised immune systems. Routes of entry are the respiratory tract and skin lesions.
- No known waterborne disease outbreaks associated with *Acanthamoeba.*

Occurrence and Exposure:

- Assumed to occur nationally in PWSs.
- Keratitis: Increased in significance during last decade which may be due to increased contact lens wear. About 700 cases in the U.S.

Preliminary Determination

- Do not regulate - regulation does not present a meaningful opportunity for risk reduction.
- Risk is primarily limited to individuals with the predisposing factors (GAE) and poor hygiene by contact lens wearers (keratitis). Guidance to encourage contact lens wearers to follow manufacturer's instructions for cleaning and rinsing their contact lenes was released for external peer review Dec. 2001

Appendix - Contaminant Profiles
Aldrin and Dieldrin

Background:

- Insecticides with similar structures
- Aldrin quickly breaks down to dieldrin, both are persistent and bioaccumulate
- From 1950-1970, popular pesticides for crops (corn and cotton)
- Banned in 1974 except to control termites, in 1987, banned all uses
- Health advisories issued in 1992 (aldrin) and 1988 (dieldrin)

Health Effect: Probable human carcinogen, effects on the liver to chronic oral exposure

Occurrence and Exposure:

- Weak geographic clustering of detections in a few southern and northeastern states
- Aldrin (cross-section data)
  - 2 (.02%) PWSs with detects (cross-section) above the estimated health effect level
  - Approximately 8,600 (.02%) people exposed
- Dieldrin (cross-section data)
  - 11 PWSs (.09%) with detects above the estimated health effect level
  - Approximately 32,000 (.07%) people exposed

Preliminary Determination :

- Do not regulate - aldrin and dieldrin do not occur with a frequency or at levels of public health concern

Appendix - Contaminant Profiles
Hexachlorobutadiene

Background:

- Used mainly as an intermediate in the manufacture of rubber compounds
- Considered a hazardous air pollutant

Health effect: Possible human carcinogen, effects on the kidney from chronic oral exposure

Occurrence and Exposure:

- Exposure occurs mainly through inadvertent inhalation at the workplace (industries that make or use this chemical)
- Two occurrence data sets:
  - Round 1 cross-section data (1988-1992) : 14 PWSs (0.11%) serving 263,000 people (0.37%) above the estimated health effect level
  - Round 2 cross-section data (1992-1997): 4 PWSs (.02%) serving 3,300 people (.005%) above the estimated health effect level

Preliminary Determination :

- Do not regulate - hexachlorobutadiene does not occur with a frequency or at levels of public health concern
- Air emissions constitute most of the on-site releases and surface water discharges have decreased significantly through the late-1990s.

Appendix - Contaminant Profiles
Manganese

Background:

- Essential nutrient, occurs naturally at low levels in soil, water, and food
- Variety of uses: production of steel, batteries, matches, animal feed, ceramics and nutritional supplements
- Secondary standard set at 0.05 mg/L

Health effect: Toxicity low when ingested. Concern - chronic exposure to high levels of manganese by inhalation in humans results primarily in central nervous system effects

Occurrence and Exposure: 32 PWSs (3.2%) serving 39,000 people (2.6%) above the estimated health effect level

Preliminary Determination:

- Do not regulate - regulation does not present a meaningful opportunity for risk reduction
- Manganese levels in drinking water from most PWSs are usually low and unlikely to significantly contribute to adverse health effects, especially when other media and pathways are considered (e.g., ingestion of food and inhalation of fumes and particles).

Appendix - Contaminant Profiles
Metribuzin

Background:

- Herbicide, applications primarily targeted to soybeans, potatoes, alfalfa, and sugar cane
- Geographic distribution of use reflects the distribution of these crops across the U.S.
- It does not volatilize readily, is very soluble in water
- Relatively persistent

Health effect: Evidence is inadequate to classify as a human carcinogen. For non-carcinogenic effects, the thyroid and liver are the most sensitive organs (impacting organ weight, serum levels, and enzyme activity).

Occurrence and Exposure: In the cross-section analysis no PWSs were above the estimated health effect level

Preliminary Determination:

- Do not regulate - does not occur with a frequency, or at levels, of public health concern
- Regional occurrence, decreasing use trends and low toxicity

Appendix - Contaminant Profiles
Naphthalene

Background: 60% of naphthalene produced is used as an intermediary in the production of resins, dyes, pharmaceuticals, and insect repellents. Crystalline naphthalene is used as a moth repellent.

Health effect: Not classifiable as a human carcinogen. Effects on the liver and eye (cataracts) after chronic exposure. High doses cause break down of the red blood cells.

Occurrence and Exposure:

- Two occurrence data sets:
  - Round 1 cross-section data (1988-1992) : 1 PWS serving 5,400 people above the estimated health effect level
  - Round 2 cross-section data (1992-1997): No PWSs were above the estimated health effect level

Preliminary Determination:

- Do not regulate - does not occur with a frequency, or at levels, of public health concern
- The data show that naphthalene detections are widespread, but detections at concentrations that represent a public health concern are rare.

Appendix - Contaminant Profiles
Sodium

Background:

- Essential nutrient, naturally occurring element
- Used in de-icing roads, water treatment chemicals, domestic water softeners, and sewage effluents

Health effects: High intake of salt may be associated with hypertension

Occurrence and Exposure: 224 PWSs (13.3%) serving 274,000 people (8%) above the estimated benchmark level

Preliminary Determination:

- Do not regulate - regulation does not present a meaningful opportunity for risk reduction
- Revise drinking water advisory
- It is not presently possible to draw definite conclusions on the benefits of reduced sodium intake because of the inconsistencies and uncertainties in the data on the relationship between sodium intake and cardiovascular disease.

Appendix - Contaminant Profiles
Sulfate

Background:

- Present in the diet, naturally occurring element
- Used for a variety of commercial purposes
- Secondary standard set at 250 mg/L (taste and odor threshold)
- SDWA requires regulatory determination be made by August 2001

Health effect: Laxative effect following high acute exposures (>500 mg/L)

Occurrence and Exposure:

- Cross section data - 300 PWSs (2%) serving 450,000 people (1%) above the estimated health effect level

Preliminary Determination:

- Do not regulate - regulation does not present a meaningful opportunity for risk reduction
- The risk of adverse health effects to the general population is limited and acute (a laxative-related response) and occurs at high drinking water concentrations (>500 mg/L, and possibly as high as >1,000 mg/L).
- Either people develop a tolerance for high concentrations of sulfate in drinking water, or they limit water consumption.
- Revise drinking water advisory

Contaminant Profile
Metolachlor

Background:

- Herbicide, primarily used on corn crops. Second most widely used pesticide in US.
- OPP will complete tolerance reassessment this Summer 2002 and issue a risk management decision document (*Tolerance Reassessment Eligibility Decision Document*).

Health Effects:

- Draft OPP risk assessment concluded that there are no drinking water risks of concern for both the parent compound and the degradates.
- Toxicology database is complete.
- OPP drinking water level of concern: 3400 ug/L

Occurrence:

- Parent compound: National occurrence, approximately 108 (in 12 different states) out of 12,953 systems with detections, but not at levels of public health concern (max. conc. = 13.8 ppb)
- Degradates. For the two degradates, OPP used two NAWQA data sets. In the state of Iowa, Metolachlor ESA was detected in 482 samples (99%) and Metolachlor OA was detected in 445 samples (92%). In the absence of more robust monitoring data, upper bound estimates were derived based on modeling.

Contaminant Profile
Perchlorate

Health Effects:

- Inhibition of thyroid function which produces the hormone that controls fetus and infant brain development and growth in older children.
- ORD released draft Risk Assessment and draft RfD in Jan. 2002, final document targeted for this fall.
- Current guidance level 4-18 ppb, current draft RfD suggests 1 ppb.
- OST may develop health advisory.

Analytical Methods:

- On March 2, 2000, EPA published an approved analytical method for perchlorate for monitoring under the Unregulated Contaminant Monitoring Rule (UCMR). At 1 ppb, perchlorate can be detected but not quantified. At 4 ppb results are quantifiable, and accurate to within plus or minus 25%.
- Recent studies show the development of analytical methods with detection limits for water samples as low as 0.05 ppb. Methods currently limited to specific analytical equipment and expertise.

Contaminant Profile
Perchlorate - Continued

Occurrence:

- Results submitted from 283 (out of 800) small systems show occurrence at levels of 4 to 7.5 ppb in four systems from four states (AZ, NC, TX, VA). Of 150 of the large systems, detections above the reporting limit of 4 ppb have been reported in 9 systems from six states -- AZ, CA (3), MD, NY, OH, PA (2). Pasadena, CA (35 ppb) and Meadville, PA (33 ppb) reported the highest levels. The remaining systems (approx. 3,000) must complete monitoring by December 2003, with submission by Spring 2004.

- California is doing a occurrence survey of 3,600 systems. Its study is also half complete. Preliminary results show 239 systems testing positive.

- Recent American Water Works Association Research Foundation (AWWARF) national occurrence study targeted both high vulnerability systems and random systems. A total of 170 source waters were identified as being vulnerable: within 4 miles for groundwater and 15 miles for surface water of 196 perchlorate manufacturing, use or receiving facilities in 39 states. 55% of these are deemed high or medium risks of contamination. 160 samples were taken and 7 were positive results (5 ground, 2 surface waters) in MD, AZ and NY. Except for MD at 507 ppb results ranged from 4-16 ppb. Samples from 138 large systems away from any known sources of perchlorate had no detection.

Contaminant Profile
Perchlorate - Continued

Treatment

- Several bench-scale or pilot-scale demonstrations of treatment technologies to remove perchlorate from groundwater or surface water have been completed (ion exchange Granular activated carbon, biological processes ozone, reverse osmosis,) The first three show the most potential. Bioreactors and ion exchange are successfully in use at Aerojet General and San Gabirel Superfund sites in CA.
- Studies are underway by universitity grantees to evaluate perchlorate treatability. Funding given by EPA to the East Valley Water District in CA was earmarked by Congress for this purpose and is administered by the American Water Works Association Research Foundation with EPA oversight. Results are expected to become available in the next 2 years.